

Applicants : Alexander Gad and Dora Lis  
U.S. Serial No.: 09/816,989  
Filed : March 23, 2001  
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Remarks

Claims 123-124, 127, 132-133, 152-153 and 155-157 were pending in the subject application. By this Amendment, applicants have amended claims 123, 133, 152 and 157. Accordingly, claims 123-124, 127, 132-133, 152-153 and 155-157 are pending in the subject application.

Support for the amendments to claims 123, 133, 152 and 157 may be found *inter alia* on page 15, lines 15-20 of the subject application.

Support for the amendments to claims 152 and 157 may be found *inter alia* on page 18, lines 28-30 and on page 19, lines 5-6 and 28-31 of the subject application.

In paragraph 3 of the February 11, 2004 Advisory Action, the Examiner stated that the new matter rejections of claims 157-165 under 35 U.S.C. § 112, first paragraph are withdrawn in light of the previously filed amendment. The Examiner also stated that the rejections of claims 123-125, 127, 129-142, and 144-166 under 35 U.S.C. § 112, second paragraph are withdrawn in light of the previously filed amendment.

However, in paragraph 5 of the February 11, 2004 Advisory Action, the Examiner maintained the enablement and written description rejections of claims 123, 124, 127, 132, 133, 152, 153, and 155-157 under 35 U.S.C. § 112, first paragraph because allegedly the term "mammal" is a genus, including species such as whale. The Examiner also alleged that there is insufficient guidance as to which species other than human and mouse model are afflicted with multiple sclerosis. The

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Examiner alleged that the specification discloses only a method for treating human afflicted with multiple sclerosis with a polypeptide consisting of SEQ ID NO: 2 or 7 using a mouse model female (SJL/J x BALB/c) mice where EAE in mice is induced with spinal cord homogenate but that there is insufficient in vivo working example demonstrating that the claimed method could treat every species in a genus.

With regard to claims 152-153, and 155-157, the Examiner alleged that other than the mouse data, there is insufficient guidance as how to predict which person in the human species, let alone which one within the genus of mammal would have multiple sclerosis. The Examiner noted that the specification discloses a mouse model where EAE is induced by injection with spinal cord homogenate but alleged that there is no showing in the specification as filed that the claimed method can delay the onset of multiple sclerosis in human.

In an Examiner-Initiated Interview Summary of a January 28, 2004 telephone conference between the Examiner and the applicants' undersigned attorney, which accompanied the February 11, 2004 Advisory Action, the Examiner provided the following recommendations: 1) The term "mammal" in claim 123, lines 1, 3, and 8 and claim 133, lines 1, 3 and 9 needs to be limited to "human" because the specification discloses only a method of treating humans using the mouse model, 2) The term "having an amino acid sequence set forth" in claim 123, lines 5-6 should be replaced with "having the amino acid sequence of which is set forth", 3) claim 127 should be rewritten to "The method of claim 123, wherein the amino acid sequence is set forth in SEQ ID NO: 2", 4) claim 132 should be rewritten to

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"The method of claim 123, wherein the amino acid sequence is set forth in SEQ ID NO: 7", 5) claims 152-153, 155-156 and 157 should be canceled or replace the word "mammal" with "mouse".

In response, the applicants have amended claims 123, 133, 152 and 157 to recite "...human..." rather than "...mammal...". Applicants have also amended claims 127 and 132 in accordance with the Examiner's comments.

Applicants have further amended claims 152 and 157 to recite "...delaying or preventing or inhibiting the progression of multiple sclerosis..." As stated above support for this amendment may be found on page 18, lines 28-30 and on page 19, lines 5-6 and 28-31 of the subject application. The cited sections of the specification support the terms "delaying", "preventing" or "inhibiting". To applicants any or all of these terms are acceptable to place the subject application in condition for allowance.

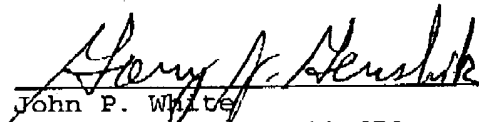
Applicants have also amended claims 152 and 157 to explicitly recite that the "...human [is] afflicted with multiple sclerosis..." so as to clarify that applicants' intention is not directed to delaying the "onset" of multiple sclerosis.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee other than the \$950.00 fee for a three-month extension of time for which authorization is hereby given, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

  
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